Registration Decision RD2014-19

Hydrogen Peroxide

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Registration Decision for Hydrogen Peroxide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of BioSafe M-70 Hydrogen Peroxide Technical Bactericide/Fungicide and ZeroTol Broad-Spectrum Algaecide/Fungicide, containing the technical grade active ingredient hydrogen peroxide, to control or prevent the buildup of fungi and algae on surfaces of greenhouse equipment and within the greenhouse irrigation waters, for the control of agricultural diseases, including rhizoctonia aerial blight, fusarium leaf spot, pseudomonas leaf spot and phytophthora root and stem rot as well as suppression of xanthomonas leaf spot and alternaria leaf spot on greenhouse and outdoor ornamentals, and to control anthracnose, brown patch and algae (green, blue-green) on turf.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2013-22, *Hydrogen Peroxide*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for hydrogen peroxide and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2013-22). This decision is consistent with the proposed registration decision stated in PRD2013-22.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2013-22, *Hydrogen Peroxide* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Hydrogen Peroxide?

Hydrogen peroxide is an oxidant, producing hydroxyl free radicals, which attacks thiol groups and double bonds of essential cell components such as lipids, proteins and DNA, inhibiting the growth of microorganisms. Hydrogen peroxide demonstrates broad-spectrum activities against fungi, bacteria and algae.

Health Considerations

Can Approved Uses of Hydrogen Peroxide Affect Human Health?

Hydrogen peroxide is unlikely to affect your health when used according to label directions.

Potential exposure to hydrogen peroxide may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Hydrogen peroxide is an oxidizing agent that is highly reactive and upon contact with moisture, degrades quickly to form water and oxygen. The body naturally produces hydrogen peroxide and detoxifying enzymes (for example, catalase and peroxidase) which control the amount of hydrogen peroxide in the body.

Technical grade hydrogen peroxide (90% concentration) is moderately toxic by the acute inhalation route in mice. At a concentration of 35%, it is considered to be severely irritating or corrosive to the eye and moderately irritating to the skin of rabbits. Consequently, the statements "Poison" and "Danger - Corrosive to eyes and skin" are required on the label. The end-use product ZeroTol Broad-Spectrum Algaecide/Fungicide is also of moderate toxicity when given as a single dose by the inhalation route to mice, and is corrosive to the eyes and moderately irritating to the skin of rabbits. Consequently, the statements "Poison" and "Danger – Corrosive to eyes and skin" are required on the label of the end-use product.

Hydrogen peroxide is a known mutagen when tested in vitro but is not genotoxic in vivo and did not cause cancer in animals. It is not expected that hydrogen peroxide would cause damage to the nervous system, have effects on reproduction, or have effects on the developing fetus. The first signs of toxicity in animals given daily doses of hydrogen peroxide over longer periods of time were decreased body weight gain and changes in blood parameters. However, after a single exposure the majority of effects observed will likely be due to the corrosive nature of hydrogen peroxide. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Risks in Residential and Other Non-Occupational Environments

Residential risks are not of concern when ZeroTol Broad-Spectrum Algaecide/Fungicide is used according to the proposed label directions

Given the rapid degradation and low residues of hydrogen peroxide expected after application, residues are not expected to remain on turf after application of this product and postapplication exposure to hydrogen peroxide is expected to be minimal following the application of ZeroTol Broad-Spectrum Algaecide/Fungicide.

Occupational Risks From Handling ZeroTol Broad-Spectrum Algaecide/Fungicide

Occupational risks are not of concern when ZeroTol Broad-Spectrum Algaecide/Fungicide is used according to the proposed label directions, which include protective measures.

Workers who mix, load or apply ZeroTol Broad-Spectrum Algaecide/Fungicide as well as workers re-entering freshly treated turf, nurseries and greenhouses can come in direct contact with ZeroTol Broad-Spectrum Algaecide/Fungicide residues on the skin or in the air. Therefore, the label specifies that anyone mixing/loading and applying ZeroTol Broad-Spectrum Algaecide/Fungicide must wear goggles or a face shield, coveralls over long-sleeved shirt and long pants, boots, chemical-resistant gloves, and a NIOSH-approved respirator. The label also requires that workers do not enter treated areas until residues have dried. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to these individuals are not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Hydrogen Peroxide Is Introduced Into the Environment?

Once introduced to the environment hydrogen peroxide transforms rapidly to water and oxygen.

Hydrogen peroxide is expected to be highly mobile in terrestrial environments after application. Adsorption to soil particles is not expected. Due to its very short half-life of less than one hour in natural soils, movement in the terrestrial environment will be limited to very short distances and leaching to ground water is not expected. Hydrogen peroxide is expected to stay in solution in aquatic environments. Partitioning and accumulation in sediment is not expected. Aquatic half-lives have been observed to be one hour to ten days.

Bioaccumulation and biomagnification are not expected. Hydrogen peroxide is toxic to non-target aquatic organisms and potentially phytotoxic to non-target plants. Based on the use pattern and short half-lives in both terrestrial and aquatic habitats, exposure to birds, mammals and beneficial arthropods is not expected.

Value Considerations

What Is the Value of ZeroTol Broad-Spectrum Algaecide/Fungicide?

ZeroTol Broad-Spectrum Algaecide/Fungicide is a broad-spectrum antimicrobial for use on greenhouse surfaces and irrigation water treatment. ZeroTol Broad-Spectrum Algaecide/Fungicide contains hydrogen peroxide that will control or prevent the buildup of fungi and algae on surfaces of greenhouse equipment and within the greenhouse irrigation waters, for example, flooded floors, flooded benches, recycled water systems, capillary mats, humidification and misting systems.

Furthermore, ZeroTol Broad-Spectrum Algaecide/Fungicide provides control of agricultural diseases, including rhizoctonia aerial blight, fusarium leaf spot, pseudomonas leaf spot and phytophthora root and stem rot as well as suppression of xanthomonas leaf spot and alternaria leaf spot on greenhouse and outdoor ornamentals. ZeroTol Broad-Spectrum Algaecide/Fungicide also controls anthracnose, brown patch and algae (green, blue-green) on turf.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of ZeroTol Broad-Spectrum Algaecide/Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with ZeroTol Broad-SpectrumAlgaecide/Fungicide on the skin or through inhalation of spray mists, anyone mixing, loading and applying ZeroTol Broad-Spectrum Algaecide/Fungicide must wear goggles or a face shield, coveralls over long-sleeved shirt and long pants, boots, chemical-resistant gloves, and a NIOSH-approved respirator.

Environment

Buffer zones of 1 to 2 meters are required for the protection of freshwater and marine habitats.

Buffer zones of 1 meter are required for the protection of terrestrial habitats.

Environmental risk mitigation statements for the disposal of waste waters and effluent from industrial and greenhouse uses are also required.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-22, *Hydrogen Peroxide)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act.*